**IN THE UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF ILLINOIS**
**EASTERN DIVISION**

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| Melanie Stacel<br><br>Plaintiff,<br><br>v.<br><br>Teva Pharmaceuticals USA, Inc.<br><br>Defendant. | Case No. 08 C 1143<br><br>Honorable Joan Gottschall |

## SECOND AMENDED COMPLAINT

Now comes the Plaintiff, Melanie Stacel, hereinafter "Plaintiff," by and through her attorney, Michael P. Cascino and complains of Defendant, Teva Pharmaceuticals USA, Inc., as follows:

## JURISDICTION AND VENUE

1. Plaintiff is an adult citizen and resident of the State of Illinois.

2. Defendant Teva Pharmaceuticals USA, Inc., hereinafter referred to as "Teva Pharmaceuticals," is a corporation which is incorporated in the State of Delaware and has its principal place of business in North America, and at all time relevant to the allegations contained herein was engaged in the business of testing, designing, manufacturing and selling a drug commonly known as minocycline and/or minocycline-containing products, hereinafter referred to as "minocycline drug" or "drug".

3. Plaintiff was diagnosed with injury on August 25, 2005, and this complaint is properly brought within the applicable statute of limitations.

4. Jurisdiction is based on diversity of citizenship of the parties hereto under Title 28, United States Code, §1332.

5. The amount in controversy exceeds the sum of Seventy-Five Thousand Dollars ($75,000), exclusive of interest and costs.

6. Venue is proper pursuant to Title 28, United States Code, §1391.

## GENERAL ALLEGATIONS

7. Plaintiff took a generic form of the drug minocycline for treatment of acute acne beginning July 9, 2004 in a 100 mg/day dosage.

8. As part of her treatment, from July 2004 forward, Plaintiff regularly took prescription minocycline for her acute acne.

9. Plaintiff purchased and consumed minocycline products which were sold, manufactured, distributed, packaged, or otherwise placed into commerce in the State of Illinois by defendant Teva Pharmaceuticals.

10. Plaintiff was ignorant of the dangerous nature of minocycline and of the nature of the risks incurred by ingesting minocycline-containing products, including developing drug-induced lupus.

11. While taking minocycline, Plaintiff developed the disease commonly known as lupus.

12. Plaintiff ceased taking minocycline on March 30, 2005. Plaintiff was diagnosed with drug-induced lupus in September of 2005.

13. As a direct and proximate result of the wrongful acts and/or omissions of Defendant, Plaintiff developed and was diagnosed as having drug-induced lupus.

14. Plaintiff would not have ingested minocycline as described herein, or would have discontinued use, or would have used safer alternative methods, had Defendant disclosed the true health consequences, risks, and adverse events, including the increased incidence and risk of drug-induced lupus and other illnesses, caused by their drug.

15. Plaintiff has suffered great pain, physical impairment, mental pain and anguish, economic losses, medical expenses, and fear of death.

**COUNT I**

**PRODUCTS LIABILITY - NEGLIGENCE**

16. Plaintiff reasserts and realleges the above jurisdiction, venue and general allegations with respect to this claim.

17. It was reasonably foreseeable by Defendant Teva Pharmaceuticals that Plaintiff and other consumers would be ingesting Defendant's minocycline drug.

18. Defendant Teva Pharmaceuticals participated in, authorized and directed the production and promotion of minocycline products without sufficient disclosure that the drug use was associated with cases of drug induced lupus.

19. Defendant Teva Pharmaceuticals had a duty to exercise reasonable care in the promotion of this drug for the safety of Plaintiff and others who were using Defendant's minocycline products.

20. At all times Defendant Teva Pharmaceuticals had a duty to comply with all Food and Drug Administration ("FDA") regulations.

21. Prior to, during, and after the time Defendant Teva Pharmaceuticals manufactured, produced, processed, packaged, designed, distributed, and/or shipped the minocycline products to which Plaintiff digested, Defendant knew, or in the exercise of ordinary or reasonable care ought to have known, that consumption of its minocycline products cause drug induced lupus.

22. Notwithstanding the aforementioned duties, Defendant Teva Pharmaceuticals was

negligent by one or more of the following acts or omissions in that Defendant:

a. Failed to adequately warn Plaintiff and/or others of the health hazards concerned with ingestion of minocycline;

b. Failed to recommend and/or provide proper cautions and warnings to physicians, to ensure Plaintiff's and/or other's safety;

c. Failed to warn Plaintiff and/or others of the danger and harm from consumption of minocycline;

d. Failed to instruct Plaintiff or others including her physician in the side effects of the drug minocycline;

e. Failed to follow FDA procedures concerning product letters of approval;

f. Failed to advise Plaintiff, the public, and physicians when promoting this drug that a side effect was drug induced lupus;

g. Failed to seek immediate changes on its label when it was aware of reported cases of drug induced lupus;

h. Failed to inform AERS (Adverse Event Reporting System) of reported cases of drug induced lupus;

i. Failed to post marketing advertisement to warn health care professionals and consumers of the potential adverse event of drug induced lupus;

j. Failed to submit proposed label revisions to the FDA to include warnings for health care professionals and consumers of the potential for the adverse event of drug induced lupus;

k. Deliberately and intentionally did not warn Plaintiff or similarly situated persons

that the drug minocycline was reported to have caused drug induced lupus.

23. As a direct and proximate result of the acts and omissions of the Defendant Teva Pharmaceuticals, Plaintiff was injured as described above.

**COUNT II**

**COMMON LAW FRAUD AND MISREPRESENTATION**

24. Plaintiff realleges the above jurisdiction, venue and general allegations.

25. Defendant Teva made false statements of material fact by not revealing to Plaintiff and others including the public and her physician and/or the FDA of reported cases in which the drug was reported to have caused what is commonly known as lupus.

26. Defendant was careless in making such false statements of material fact to the public via promotional activities, letters of approval to the FDA, labels attached to the prescription for users, dissemination of information to physicians including Plaintiff's physician and failures to ask the FDA to put complete information on the labels that users would be fully informed as to what Defendant knew about the drug could causing lupus in certain persons and by not revealing Defendant's full knowledge about cases of drug induced lupus.

27. The failure of Defendant to reveal full knowledge about this drug causing a lupus condition to Plaintiff, the public and the FDA was intended to cause persons including Plaintiff to purchase the drug.

28. Plaintiff, in reliance of the truth of the statements concerning the drug's safety, took the medication and continued to take the medication without knowledge that it was causing drug induced lupus.

29. Plaintiff, in reliance of the material omission and/or concealment by Defendant of its full knowledge about the drug being reported to cause drug induced lupus, took the drug.

30. Defendant owed a duty to Plaintiff, the public, physicians and the FDA to fully disclose and competently disclose that this drug could cause lupus.

31. As a direct and proximate cause of Defendant's misrepresentations, Plaintiff was injured in that she got lupus from the Defendant's drug.

## COUNT III

## ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT

32. Plaintiff realleges the jurisdiction, venue and general allegations.

33. The Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1, *et seq*., provides statutory relief for persons like Plaintiff who have been injured including by drug sellers like Defendant herein.

34. In violation of the Illinois Consumer Fraud and Deceptive Business Practices Act, Defendant committed deceptive acts and practices including:

a. Failed to tell Plaintiff, the public, physicians and the FDA that there were reported cases of this drug inducing lupus;

b. Concealed a material fact that certain persons would develop drug induced lupus;

c. Failed to adequately warn Plaintiff and/or others of the health hazards concerned with ingestion of minocycline;

d. Failed to recommend and/or provide proper cautions and warnings, to ensure Plaintiff's and/or other's safety;

e. Failed to warn Plaintiff and/or others of the danger and harm from consumption of

minocycline;

f. Failed to instruct Plaintiff or others in the use of precautionary measures in relation to minocycline;

g. Failed to follow FDA procedures concerning product letters of approval;

h. Failed to advise Plaintiff, the public, and physicians when promoting this drug that a side effect was drug induced lupus;

i. Failed to seek immediate changes on its label when it was aware of reported cases of drug induced lupus;

j. Failed to inform AERS (Adverse Event Reporting System) of reported cases of drug induced lupus;

k. Failed to post marketing advertisement to warn health care professionals and consumers of the potential adverse event of drug induced lupus;

l. Failed to submit proposed label revisions to the FDA to include warnings for health care professionals and consumers of the potential for the adverse event of drug induced lupus;

m. Deliberately and intentionally did not warn Plaintiff or similarly situated persons that the drug minocycline was reported to have caused drug induced lupus.

35. Defendant intended that by not disclosing and/or concealing the material fact that there were reported cases of drug induced lupus, physicians would prescribe the drug and the public including Plaintiff would purchase the drug.

36. The aforementioned deception occurred in the course of conduct involving trade or commerce.

37. Defendant's aforementioned deception was a proximate cause of Plaintiff's injury, namely her drug induced lupus.

**COUNT IV**

**PUNITIVE DAMAGES**

38. Plaintiff realleges the above jurisdiction, venue and general allegations.

39. That Defendant acted willfully and/or with such gross negligence as to indicate a wanton disregard for others' rights including Plaintiff herein in the aforementioned Defendant's conduct described in the above paragraphs.

40. That Defendant continues to omit and conceal that the drug minocycline can cause drug induced lupus in certain individuals constitutes such gross negligence as to indicate a wanton disregard for others' rights including Plaintiff, the public, and the FDA.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for relief as follows: judgment against Defendant, Teva Pharmaceuticals USA, Inc., for compensatory and general damages in excess of $100,000 plus costs.

Dated this 28th day of March, 2008

Respectfully submitted,

s/ Michael P. Cascino

One of the Plaintiff's Attorneys
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